



6712-01

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 5

[ET Docket Nos. 10-236 and 06-155; FCC 16-86]

Radio Experimentation and Market Trials –Streamlining Rules

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Commission modifies its rules to permit program experimental radio licensees (program licensees) to experiment with radio frequency (RF)-based medical devices on certain restricted frequencies, if the medical device being tested is designed to comply with applicable Commission service rules. Adoption of this proposal facilitates access to spectrum that can be used under an experimental program license to improve the utility of this type of licensing scheme for those entities experimenting with RF-based medical devices, and thereby help to advance innovation in this area. This action will result in no harm to any qualified license applicant or licensee.

DATES: Effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]

FOR FURTHER INFORMATION CONTACT: Rodney Small, Office of Engineering and Technology, 202-418-2452, Rodney.Small@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Second Report and Order, ET Docket No. 10-236 and 06-155, FCC 16-86, adopted June 29, 2016, and released June 30, 2016. The full text of this document is available for inspection and copying during normal business hours in the FCC Reference Center (Room CY-A257), 445 12th Street,

SW., Washington, DC 20554. The complete text of this document also may be purchased from the Commission's copy contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room, CY-B402, Washington, DC 20554. The full text may also be downloaded at:

https://apps.fcc.gov/edocs_public/Query.do?numberFld=16-

86&numberFld2=&docket=&dateFld=&docTitleDesc. People with Disabilities: To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an e-mail to fcc504@fcc.gov or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

This document does not contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104-13.

Synopsis

1. In 2013, the Commission established in the Report and Order in this proceeding, 78 FR 25137, April 29, 2013, three new kinds of experimental licenses – including program licenses – designed to benefit the development of new technologies and expedite their introduction to the marketplace. In this Second Report and Order, the Commission adopts the proposal set forth in the Further NPRM, 80 FR 52437, August 31, 2015, by modifying section 5.303 of its rules for program licenses to permit experimentation in the restricted frequency bands for medical devices that comply with the service rules in Part 18 (Industrial, Scientific, and Medical Equipment), Part 95 Subpart H (Wireless Medical Telemetry Service), or Part 95 Subpart I (Medical Device Radiocommunication Service). This rule change will establish parity between all qualified medical device manufacturers and developers—whether they are health care institutions or medical device manufacturers—as to permissible frequencies of operation for conducting basic research and clinical trials with RF-based medical devices. Accordingly,

because the Commission finds that the proposal will serve the public interest by promoting medical innovation with no detriment to the public, it adopts that proposal. Revised section 5.303 of the rules is set forth at the end of this summary.

Regulatory Flexibility Certification

2. The Regulatory Flexibility Act (RFA)¹ requires that agencies prepare a regulatory flexibility analysis for notice-and-comment rulemaking proceedings, unless the agency certifies that “the rule will not have a significant economic impact on a substantial number of small entities.”² Modification of section 5.303 of the Commission’s Rules establishes parity between all qualified medical device manufacturers as to permissible frequencies of operation for conducting basic research and clinical trials with RF-based medical devices. The Commission previously determined that “[t]he entities affected by the proposed rule change are equipment manufacturers seeking to test medical equipment designed to operate in the restricted frequency bands listed in section 15.205(a) of the rules, and such manufacturers are limited in number,” and certified that the proposed rules would not have a significant economic impact on a substantial number of small entities. The Commission received no comments that addressed this determination or that claimed that the proposal requires additional RFA analysis. The Commission therefore certifies that the rule revisions set forth herein will not have a significant economic impact on a substantial number of small entities.

¹ See 5 U.S.C. 604. The RFA, *see* 5 U.S.C. 601 *et seq.*, has been amended by the Contract with America Advancement Act of 1996, Public Law 104-121, 110 Stat. 847 (1996) (CWAAA). Title II of the CWAAA is the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA).

² 5 U.S.C. 605(b).

Congressional Review Act

3. The Commission will send a copy of this Second Report and Order in a report to Congress and the Government Accountability Office pursuant to the Congressional Review Act, see 5 U.S.C. 801(a)(1)(A).

ORDERING CLAUSES

4. Accordingly, IT IS ORDERED, that, pursuant to sections 301 and 303 of the Communications Act of 1934, as amended, 47 U.S.C. 301 and 303, and §§ 1.1 and 1.425 of the Commission's rules, 47 CFR 1.1, 1.425, this Second Report and Order IS ADOPTED.

5. IT IS FURTHER ORDERED that part 5 of the Commission's rules, 47 CFR part 5, IS AMENDED, as set forth in the Rule Changes. These revisions will be effective **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

6. IT IS FURTHER ORDERED that, if no applications for review are timely filed, this proceeding SHALL BE TERMINATED and the docket CLOSED.

List of Subjects in 47 CFR Part 5

Radio, Reporting and recordkeeping requirements.

FEDERAL COMMUNICATIONS COMMISSION.

Marlene H. Dortch,
Secretary.

Rule Changes

For the reasons set forth in the preamble the Federal Communications Commission amends 47 CFR part 5 as follows:

PART 5 -- EXPERIMENTAL RADIO SERVICE

1. The authority citation for part 5 continues to read as follows:

Authority: Secs. 4, 302, 303, 307, 336 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 302, 303, 307, 336. Interpret or apply sec. 301, 48 Stat. 1081, as amended; 47 U.S.C. 301.

2. Section 5.303 is revised to read as follows:

§ 5.303 Frequencies.

(a) Licensees may operate in any frequency band, including those above 38.6 GHz, except for frequency bands exclusively allocated to the passive services (including the radio astronomy service). In addition, licensees may not use any frequency or frequency band below 38.6 GHz that is listed in § 15.205(a) of this chapter.

(b) Exception: Licensees may use frequencies listed in § 15.205(a) of this chapter for testing medical devices (as defined in § 5.402(b) of this chapter), if the device is designed to comply with all applicable service rules in part 18; part 95, subpart H; or part 95, subpart I of this chapter.

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